UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

(H)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/621,725	03/21/96	LEHMANN P	CASE-02135

HM12/0209

PETER G CARROLL
MEDLEN AND CARROLL
SUITE 2200
220 MONTGOMERY STREET
SAN FRANCISCO CA 94104

EXAMINER	
SCHWADRON, R	
ART UNIT	**PAPER NUMBER**
1644	16

DATE MAILED: 02/09/99

Please find below and/or attached an Office communication concerning this application or pr ceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/621,725	Lehmann et al.
Examiner	**Group Art Unit**
Ron Schwadron, Ph.D.	1644

☐ Responsive to communication(s) filed on _____ .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1, 4-8, 18, 20, and 21* is/are pending in the application.

Of the above, claim(s) *4-8* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1, 18, 20, and 21* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

15. Claims 1,2,18,20,21 are under consideration. Claim 18 has been amended. Claims 20 and 21 are newly added.

RESPONSE TO APPLICANTS ARGUMENTS

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claim 1 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Namikawa et al. in view of Tobin et al. (US Patent 5,674,978) and prior art disclosed in the specification (Alvord et al., Zamvil et al., Kimball). Applicants arguments have been considered and deemed not persuasive.

The claim is drawn to the method of claim 1. Namikawa et al. teach that immunization with MBP in IFA prevents EAE in rats (see page 932, first column, first paragraph). The specification discloses that the art recognizes certain similarities between EAE and human MS (see page 2, first paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed method because Namikawa et al. teach that immunization with MBP in IFA prevents EAE in rats and the art recognized similarities between EAE and human MS. One of ordinary skill in the art would have been motivated to do the aforementioned because Tobin et al. teach treatment with autoimmune antigens for the treatment of human disease.

Regarding applicants comments in the instant amendment about Namikawa et al., Namikawa et al. teach that "Furthermore, repeated injections of BP/IFA prevent subsequent induction of experimental allergic encephalomyelitis by BP emulsified in complete Freund's

adjuvant."(see Abstract). Regarding applicants comments in the instant amendment about Namikawa et al. and the issue of whether spleen cells from immunized rats can or cannot transfer disease, the claimed invention is not drawn to a method of treatment with spleen cells from an immunized donor. The claimed invention is drawn to a method of immunizing with MBP. Namikawa et al. teach that, "Furthermore, repeated injections of BP/IFA prevent subsequent induction of experimental allergic encephalomyelitis by BP emulsified in complete Freund's adjuvant."(see Abstract). Applicants arguments about spleen cells from immunized rats and the issue of whether said cells can or cannot transfer disease is irrelevant to the issue under consideration because the claimed invention is drawn to a method of immunizing with MBP and Namikawa et al. teach that immunization of rats by injection of BP in IFA prevents subsequent active or passive induction of EAE (page 932, first column, first paragraph) in every treated individual.

Regarding applicants comments about motivation to create the claimed invention, the M.P.E.P., section 2144 (July 1998), page 2100-115 teaches that with regards to the rationale/motivation supporting a rejection under 35 U.S.C. 103 that:

> *RATIONALE MAY BE IN A REFERENCE, OR REASONED FROM COMMON KNOWLEDGE IN THE ART, SCIENTIFIC PRINCIPLES, ART - RECOGNIZED EQUIVALENTS, OR LEGAL PRECEDENT*
>
> *The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. In re Fine , 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones , 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). See also In re Eli Lilly & Co ., 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) (discussion of reliance on legal precedent); In re Nilssen , 851 F.2d 1401, 7 USPQ2d 1500, 1502 (Fed. Cir. 1988) (references do not have to explicitly suggest combining teachings); Ex parte Clapp , 227 USPQ 972 (Bd. Pat. App. & Inter. 1985) (examiner must present convincing line of reasoning supporting rejection); and Ex parte Levengood , 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993) (reliance on logic and sound scientific reasoning).*

In the instant rejection, the motivation to combine the references is reasoned from knowledge

generally available to one of ordinary skill in the art and established scientific principles. Namikawa et al. teach that immunization with MBP in IFA prevents EAE in rats, the art recognizes certain similarities between EAE and human MS (see page 2, first paragraph) and Tobin et al. teach treatment with autoimmune antigens for the treatment of human disease. Regarding applicants comments about Tobin, Namikawa et al. teach that, "Furthermore, repeated injections of BP/IFA prevent subsequent induction of experimental allergic encephalomyelitis by BP emulsified in complete Freund's adjuvant."(see Abstract). Thus, Namikawa et al. teach that immunization with MBP in IFA prevents EAE in rats (see page 932, first column, first paragraph), while the specification discloses that the art recognizes certain similarities between EAE and human MS (see page 2, first paragraph). Tobin et al. teach treatment with autoimmune antigens for the treatment of human disease. The disclosure of Namikawa et al. teaches that immunization with MBP in IFA prevents EAE in rats and this disclosure is commensurate with the only experimental data disclosed in the specification (treatment of EAE in mice). According to the prior art disclosed in the specification (Alvord et al., Zamvil et al., Kimball), the art recognizes that EAE is a model for MS and therefore the treatment as disclosed by Namikawa et al. should be applicable to humans. Tobin et al, merely confirms that treatment with autoimmune antigens for the treatment of human disease is known in the art.

18. Claims 1,2,18,20,21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Namikawa et al. in view of Tobin et al. (US Patent 5,674,978) and prior art disclosed in the specification (Alvord et al., Zamvil et al., Kimball) as applied to claim 1 above, and further in view of Goodwin et al. (US Patent 5,569,585) and Oprandy (US Patent 5,200,312).

The previous paragraph makes obvious the claimed invention except for the use of the immunoassay recited in the claims. Namikawa et al. teach that after immunization, the response of cells to a T cell mitogen is tested (see Table 3 and page 934, column 1). The response of T cells would have been alternatively measured using art known lymphokine assays, because the art recognizes that activated T cells produce lymphokines in response to antigenic stimulation (see Goodwin et al., see column 10, penultimate paragraph). ELISA assays for T cell cytokines are known in the art as is the membrane recited in claim 2 (see specification, page 8, first paragraph and Goodwin et al., column 10). Oprandy teaches the use of antibody coated PVDF membranes in immunoassays (see column 3 and Example 1). Oprandy teaches that the use of antibody coated

PVDF membranes in immunoassays results in improved sensitivity (see column 3, first paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because the previous rejection makes obvious the claimed invention except for the use of the immunoassay recited in the claims, while Namikawa et al. teach that after immunization, the response of cells to a T cell mitogen is tested and the response of T cells would have been alternatively measured using art known lymphokine assays, because the art recognizes that activated T cells produce lymphokines in response to antigenic stimulation (see Goodwin et al., see column 10, penultimate paragraph), ELISA assays for T cell cytokines are known in the art and Oprandy teaches that the use of antibody coated PVDF membranes in immunoassays results in improved sensitivity. One of ordinary skill in the art would have been motivated to do the aforementioned because Namikawa et al. teach that after immunization, the response of cells to a T cell mitogen is tested and the response of T cells would have been alternatively measured using art known lymphokine assays, because the art recognizes that activated T cells produce lymphokines in response to antigenic stimulation. One of ordinary skill in the art would have been also been motivated to do the aforementioned because Oprandy teaches that the use of antibody coated PVDF membranes in immunoassays results in improved sensitivity.

Regarding applicants comments in the instant amendment as they apply to this new ground of rejection, Goodwin et al. teach that activated T cells produce lymphokines in response to antigenic stimulation and that these lymphokines can be measured in immunoassays (see column 10, penultimate paragraph). Regarding applicants comments about Viselli e al., Viselli et al. is not cited in the instant rejection. Oprandy teaches the use of antibody coated PVDF membranes in immunoassays (see column 3 and Example 1). Oprandy teaches that the use of antibody coated PVDF membranes in immunoassays results in improved sensitivity (see column 3, first paragraph).

19. No claim is allowed.

20. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 305-

3014.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800 1606

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644
February 8, 1999